

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

KM

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/181,671 10/29/98 MEISEL

P PM256868

HM12/0103

EXAMINER

PILLSBURY MADISON & SUTRO  
I P GROUP  
NINTH FLOOR EAST TOWER  
1100 NEW YORK AVENUE N W  
WASHINGTON DC 20005-3918

DAVIS, B

ART UNIT	PAPER NUMBER
----------	--------------

1621

13

DATE MAILED:

01/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER OF  
PATENTS AND TRADEMARKS  
Washington, D.C. 20231

**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 13

Application Number: 09/181,671

Filing Date: 10/29/98

Appellant(s): Meisel et al.

Date mailed 1/3/01.

---

Ann S. Hobbs  
For Appellant

**EXAMINER'S ANSWER**

This is in response to appellant's brief on appeal filed 11/28/00.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief. There are no related appeals or interferences.

Art Unit: 1621

**(3)     *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4)     *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5)     *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6)     *Issues***

The appellant's statement of the issues in the brief is correct.

**(7)     *Grouping of Claims***

Appellant's brief includes a statement that claims 1-3 and 16 do not stand or fall together as set forth in 37 CFR 1.192(c)(7) and (c)(8).

**(8)     *ClaimsAppealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9)     *Prior Art of Record***

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

Art Unit: 1621

Kirk-Othmer Encyclopedia of Chemical Technology, 4th. Ed., John Wiley and Sons, Inc., 1993, pp. 700-702.

**(10) *Grounds of Rejection***

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-3 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 4200259 and further in view of the *Kirk-Othmer Encyclopedia of Chemical Technology*, 4th ed., Vol 7, 1993, pp. 700-702.

DE 4200259, as appellant admits on page 1 lines 24-29 of the specification, teaches that the compound of formula I is well-known in the art, as is its use in pharmaceutical compositions.

*Kirk-Othmer Encyclopedia of Chemical Technology*, 4th. Ed., John Wiley and Sons, Inc., 1993, pp. 700-702, teaches that polymorphism is a condition in which a specific chemical compound may crystallize in different forms, that is, different space groups and with different physical and physico-chemical properties. An example is given of a simple compound, ammonium nitrate, with four form changes. In the paragraph which follows, it is stated that a specific polymorph may be absolutely essential for a particular crystalline product. By way of example, it is generally stated that one polymorph may have more desirable physico-chemical properties, i.e. color, hardness, solubility or stability, than another.

Appellant distinguishes over the prior art in that the compound of formula I has been discovered to crystallize in three distinct crystalline forms. This is an instance of

Art Unit: 1621

polymorphism. However, this does not render the compound in these crystalline forms patentable over the compound itself. The compound is neither new nor novel, nor is its claimed use.

As the above section of the Kirk-Othmer reference makes quite clear, it is generally known in the chemical arts that many compounds crystallize in two or more distinct forms, morphologies, and that these forms will have distinct properties, with some forms, because of such properties, being more desirable/useful than others. This is the basis for the examiner's assertion that the three crystalline morphologies (A, B and C) of the compound of formula I are inherent in the prior art.

It would have been obvious to one of ordinary skill in the art at the time of the invention that the three crystalline forms claimed by appellant were intrinsic to the compound of the prior art, motivated by the fact that it is well known in the chemical arts that crystal polymorphism is a common and commonly recognized property of crystalline compounds.

Art Unit: 1621

**(11) Response to Argument**

Appellant argues that a prima facie case of obviousness has not been presented. The examiner respectfully disagrees. As appellant points out, a prima facie case of obviousness is established if the prior art suggests to one of ordinary skill in the art to modify the prior art in such a fashion as to produce the claimed invention, and that such a modification would reasonably be expected to succeed. The examiner maintains that the DE 4200259 reference teaches the compound, and the Kirk-Othmer reference teaches its modification and the provides the motivation to perform such a modification.

The examiner respectfully suggested (Paper No. 8) that applicants submit a declaration which contains a side-by-side comparison of the diffraction pattern of the prior art crystals with the three diffraction patterns of the instant claims. Then, following the reasoning of In re Gross and Flanigen 201 USPQ 57, 1979, CCPA, if it could be persuasively shown that the diffraction patterns are indeed different and distinct, then the instant claims would be allowable, provided that the prior art does not enable the preparation of the instantly claimed forms.

In support of appellant's arguments, appellant has submitted the requested declaration. Two separate batches of the compound were prepared. The first batch was, as shown by X-ray powder diffraction, shown to be a mixture of modification (applicant's term) C and A. The second batch was shown to be a mixture of modification A and B. That is, the crystalline

Art Unit: 1621

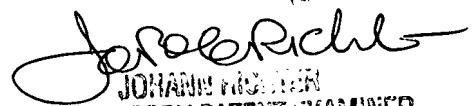
modifications (A, B and C) of the compound of formula I are shown by the X-ray data to be inherent to the prior art compound.

Appellant claims that the three modifications have different and distinct physicochemical properties. The examiner is in perfect agreement, but maintains that given the Kirk-Othmer reference such differences would have been expected. Appellant argues at some length that the examiner has merely applied 'an obvious to try' standard in determining patentability. For an invention to be obvious, two things must be found in the prior art: 1) the suggestion of the invention, and 2) the expectation of its success. As stated above, the DE 4200259 reference teaches the compound, and Kirk-Othmer reference teaches its modification and provides the motivation to perform such a modification. The examiner is in perfect agreement with the appellant that neither of the cited references teaches the particular X-ray data associated with each modification, and which is the basis of appellant's claims. However, the examiner believes that the Kirk-Othmer reference makes it clear, both in the text and by the detailed examples, that polymorphism is a well-recognized phenomenon in the chemical arts and that this is a general and well-known property of crystals - all crystals, including appellant's crystals. That being the case, the examiner fails to see why appellant considers the examiners rejection 'a proverbial fishing expedition' when one of ordinary skill in the art would have recognized the possibility of crystal polymorphism and been motivated to separate what polymorphs a crystalline composition might contain in order to find a particular polymorph with desirable properties.

Art Unit: 1621

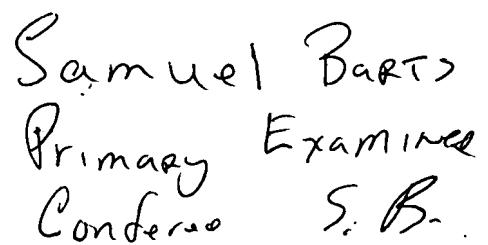
For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

  
Johann Richter  
SUPERVISORY PATENT EXAMINER  
GROUP 1600

  
BJD  
December 27, 2000

Ann S. Hobbs  
1100 New York Avenue, NW  
Ninth Floor - East Tower  
Washington, D.C. 20005-3918

  
Samuel Bart  
Primary Examiner  
Confereo S. B.

  
SREENI PADMANABHAN  
PRIMARY EXAMINER